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Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	January 10, 2014
Contact Person and Address:	Bradley Heil Regulatory Affairs Specialist T (901) 399-6339 F (901) 566-7831
Name of Device:	Smith & Nephew, Inc. Patient Matched Cutting Blocks
Common Name:	Knee Prosthesis
Device Classification Name and Reference:	CFR 888.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis 21 CFR 888.3565 Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	OOG, JWH, MBH

Device Description
The Patient Matched Cutting Blocks were previously cleared for market via premarket notification K082358. Subject of this premarket notification are modifications to the software components used to design and manufacture the Patient Matched Cutting Blocks. The Patient Matched Cutting Blocks are designed and manufactured from patient imaging data (MRI, X-Ray).

Technological Characteristics
Software verification and validation testing was completed in line with FDA's guidance document entitled, "General Principles of Software Validation; Final Guidance for Industry and FDA Staff," dated January 11, 2002. A review of this testing has demonstrated that there are no new issues related to the safety and effectiveness of the subject device and the software will perform as intended. Clinical data was not needed to support the safety and effectiveness of the subject devices.

Intended Use
Smith & Nephew's Patient Matched Cutting Blocks are intended to be used as patient-specific surgical instrumentation to assist in the positioning of total knee replacement components intra-operatively and in guiding the marking of bone before cutting provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

The Patient Matched Cutting Blocks are intended for use with the following existing Smith & Nephew, Inc. knee systems and their cleared indications for use:

- Genesis 2 Knee System
- Legion Knee System
- Journey BCS Knee System
- Journey II Knee System

The Patient Matched Cutting Blocks are intended for single use only.

Performance Data
Smith & Nephew conducted a cadaveric assessment of the subject devices. The results of this study show that the patient matched cutting blocks designed using the case processing applications perform equivalent to conventional instrumentation or within clinically acceptable parameters with respect to resection depth, coronal alignment (varus/valgus), rotation and tibial posterior slope.

Substantial Equivalence Information
The subject devices are identical in function, intended use, indications for use, and material composition, and very similar in overall design to the Patient Matched Cutting Blocks cleared via premarket notification K082358.

Table 1: Substantially equivalent predicates to the modified Patient Matched Cutting Blocks

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	Patient Matched Cutting Blocks	K082358	11/25/2008

Conclusion
As previously noted, this Traditional 510(k) Premarket Notification is being submitted to request clearance for the modified Patient Matched Cutting Blocks. Based on the similarities to the predicate components, a cadaveric assessment, and a review of the software validation testing performed, the devices are substantially equivalent to above predicate Patient Matched Cutting Blocks.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 28, 2104

Smith & Nephew, Inc.
Mr. Bradley Heil
Regulatory Affairs Specialist
1450 Brooks Road
Memphis, Tennessee 38116

Re: K130708
Trade/Device Name: Smith & Nephew Patient Matched Cutting Blocks
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.
Regulatory Class: Class II
Product Code: JWH, MBH, OOG
Dated: October 29, 2013
Received: October 30, 2013

Dear Mr. Heil:

This letter corrects our substantially equivalent letter of December 11, 2013.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent J. Devlin -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130708

Device Name: Smith & Nephew, Inc. Patient Matched Cutting Blocks

Indications for Use:

Smith & Nephew's Patient Matched Cutting Blocks are intended to be used as patient-specific surgical instrumentation to assist in the positioning of total knee replacement components intra-operatively and in guiding the marking of bone before cutting provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

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Prescription Use X
(Part 21 CFR 801 Subpart D) AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices